INTRODUCTION:

This document provides a policy for management of policies which includes its preparation, review, approval and implementation.

SCOPE:

This policy applies to all GxP policies prepared for ……. and its associated units.

POLICY DETAILS:

- ✧ There shall be written procedure for preparation, review, approval and implementation of policies. The contents of this policy shall meet at the minimum regulatory requirements.
- ✧ The contents of Policies shall provide good guidelines and expectations to ensure fair and consistent practices and legal compliance.
- ✧ Each policy shall undergo a review and approval procedure by the authorised signatories before implementation.
- ✧ Gap analysis shall be performed by each site while implementing the policy and initiate action plans to bridge the identified gaps, if any.
- ✧ Exemption to policy shall only be made to support specific market requirement(s), in such cases minimum local regulatory requirements shall be met.
- ✧ All non-compliance to requirements specified in the policies shall be reported in Quality Management review and escalated to the management for further action.
- ✧ In case of divergent views in documents, the content of policy shall prevail over all other documents.
- ✧ The policies shall be reviewed at specified interval and shall be amended whenever there is a major change in company quality policy and/or regulatory requirements.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION:

Policy:

A Policy is a principle or protocol to guide for taking decisions and achieve rational outcome. A Policy is also a statement of intent, and is implemented as a procedure or protocol.

GxP (GxP Regulation):

The underlying international pharmaceutical requirements, such as those set forth in US FD&C Act, US PHS Act, FDA regulation, EU Directives, Japanese regulations, or other applicable national legislation or regulations under which a company operates. These include but are not limited to:
Good manufacturing practices (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Distribution Practice (GDP), Good Quality Practice (GQP), Medical Device Regulations, and Prescription Drug Marketing (PDMA)

ABBREVIATIONS:

EU	:	European Union
FDA	:	Food And Drug Administration
GxP	:	Good X Practices where x stands for manufacturing, laboratory, clinical, distribution
US FD&C	:	United States Federal Food, Drug, and Cosmetic Act
US PHS	:	United States Public Health Service

REFERENCES: Not Applicable